201-15414

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06/29/2004 10:11 AM

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Subject: Environmental Defense comments on Alkenes, C6-C10, Hydroformylation Products, High Boiling (CAS# 68526-82-9)

(Submitted via Internet 6/28/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and erauckman@charter.net)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Alkenes, C6-C10, Hydroformylation Products, High Boiling (CAS# 68526-82-9).

The test plan and robust summaries for the Alkenes, C6-10, hydroformylation products, high boiling fraction, also known by its trade name EP-290, were submitted by BASF Corporation. Overall the submission is complete and informative. EP-290, according to the test plan, is the residue remaining from the distillation of aliphatic alcohols from a hydroformylation reaction product. A number of other reactions occur, and EP-290 is a mixture containing primarily long-chain aliphatic alcohols esters and alkenes. The sponsor provided considerable data on the composition and chemistry of EP-290. Although these data added considerably to the length of the submission, we found it essential to our review.

The test plan states that EP-290 is produced in a closed system with little opportunity for worker exposure. EP-290 has a number of commercial and industrial applications, including use as a antifoamer/defoamer, a lubricant in textile manufacture, leather processing and coal mining. No information is provided on environmental or human exposure as a consequence of these applications.

The sponsor contends that existing data are adequate to meet the requirements of the HPV program. This contention is based on the use of data from Monsanto Chemical Company on a similar mixture, termed heavy-oxo ends (HOE), and the availability of data for several of the individual constituents of EP-290. BASF purchased the hydroformylation business from Monsanto and uses the same process and equipment to produce EP-290, so it does seem reasonable to use existing data on HOE, as the two mixtures should be very similar. However, to support this argument, the sponsor should provide composition data on HOE in the revised test plan; it seems likely that this information would have been provided when BASF purchased the business and the equipment. The robust summaries also include a number of studies on some of the individual constituents of EP-290. These data reasonably represent the major categories of chemicals found in EP-290, particularly the olefins and alcohols. Therefore, we agree with the sponsor that no new studies are necessary for EP-290 under the guidelines of the HPV program.

Specific comments are as follows:

1. Since EP-290 is a mixture, the sponsor provides data for many of the constituents for the physiochemical endpoints and biodegradation. These

data are sufficient to address these endpoints. The alkenes seem to be most resistant to biodegradation and therefore are of potential concern for environmental contamination.

2. The Executive Summary states that EP-290 is toxic to fish, aquatic invertebrates and algae. Examination of the data show that while this statement is true for aquatic invertebrates and algae, fish do not appear to be sensitive, based on two studies that report EC 50 values of >1000mg/L. This discrepancy should be resolved.

3. The sponsor presents considerable data on the metabolism of individual constituents of EP 290. This information is helpful in justifying the use of data from those constituents.

4. The inhalation repeat dose study, using HOE as the test substance, indicates that the observed lung toxicity occurs following relatively high doses. Histological analyses did not reveal any lesions of the reproductive tracts from these animals. This information, along with essentially negative findings in developmental toxicity studies on representative alkenes and alcohols, is used to conclude that reproductive studies are not necessary. We agree with this conclusion with one caveat. We recommend that the sponsor conduct an in vitro screen for hormonal activity using EP-290 and/or its major constituents as the test substance(s). If this screen turns up positive, then reproductive toxicology studies should be conducted.

Thank you for this opportunity to comment.

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